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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,010	09/08/2004	Susumu Kuwabata	43888-332	8864

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,010	KUWABATA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 08 September 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 09/08/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending in this application and were examined on their merits.

Claim Objections

Claim 5 is objected to because of the following informalities: It is noted that claim 6 uses the notation of a (+) sign to denote positive voltage relative to the most negative potential while Claim 5 uses the word "negative" to denote negative voltage relative to the most negative potential . Appropriate correction is required.

Claim 11 is objected to because of the following informalities: The oxidoreductase **pylo**roquinoline is misspelled if it is referring to **pyrro**loquiniline. A search for **pylo**roquinoline was unsuccessful. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5 and 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 in part (a) references a counter electrode "under the existence" of a reagent system. It is unclear as it is written exactly what is meant by that phrase. Claims 5 and 6 are written in a manner in which it is exceedingly difficult to ascertain what exactly is being claimed, especially for one not skilled in the art of electrochemistry.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda *et al.* (U.S. 6,340,428 B1)

Ikeda *et al.* discloses a method for quantitating a substrate in a sample solution, which may contain dissolved interfering substances using an electrode system and a reagent system, comprising the steps of:

Supplying a sample solution containing substrate and potential interfering substances to an electrode system comprising a working electrode and counter electrode under a reaction layer containing oxidoreductase (glucose oxidase) and an electron mediator; applying an potential to the working electrode to cause a redox reaction of the electron mediator; measuring the electric signal produced; and quantitating the amount of substrate based on the signal. (Column 12, Claim 5).

Ikeda *et al.* teaches that the working electrode and counter electrode are on the same plane, and are in positions opposed to each other across a space. (Fig. 1)

Ikeda does not specify whether it is AC or DC current that supplies the potential to the working electrode, however since both positive and negative voltages are used in the working examples and it is known in the art that AC current can be either + or – while DC current is positive only that for purposes of examination the teachings of Ikeda *et al.* encompass both AC and DC currents.

Ikeda *et al.* teaches the use of a reference (third electrode). (Column 12, Claim 5)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda *et al.* (U.S. 6,340,428 B1) in view of Kuwabata *et al.* (2001), Crumbliss *et al.* (1986), Higgins (1987) and Ju *et al.* (1998).

The teachings of Ikeda *et al.* were discussed *supra.*

Ikeda *et al.* does not teach wherein a central potential of the AC potential is within the range of –0.4 to +0.4 V relative to a redox potential of said electron mediator, and is a potential more positive than a potential that is - 0.05 V relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion-controlled.

Ikeda *et al.* does not teach wherein a central potential of the AC potential being within the range of –0.1 to +0.1 V relative to a redox potential of said electron mediator, and is a potential more positive than a potential that is + 0.05 V relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion-controlled.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the electric signal that is measured is impedance.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the working electrode is a rotating disk electrode or micro-electrode.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the electron mediator is ferrocene carboxylic acid.

Ikeda *et al.* does not teach a method of quantitating a substrate in which the oxidoreductase is pyrroquinoline quinone-dependent glucose dehydrogenase, and the electron mediator is ruthenium hexacyanate.

Kuwabata *et al.* teaches the step of applying an AC potential to the working electrode to cause a redox reaction of the electron mediator characterized by the central potential (0.5 V) of the AC potential being within the range of –0.4 to 0.4 V (0.18 V) relative to a redox potential of the electron mediator ferrocene carboxylic acid (0.32 V), and is a potential that is –0.05 relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion controlled. (Page 1, Lines 16-18 and Page 2, Line 20-25)

Kuwabata *et al.* teaches the step of applying an AC potential to the working electrode to cause a redox reaction of the electron mediator characterized by the central potential (0.5 V) of the AC potential being within the range of –0.1 to 0.1 V (0.09 V) relative to a redox potential of the electron mediator ferrocene carboxylic acid (0.23 V), and is a potential that is 0.05 relative to the most negative potential in a potential region where the reaction of an interfering substance at the working electrode is diffusion controlled. (Page 1, Lines 16-18 and Page 2, Line 20-25)

Kuwabata *et al.* teaches a method of quantitating a substrate in which the electric signal that is measured is impedance. (Page 2, Lines 19-20)

Kuwabata *et al.* teaches a method of quantitating a substrate in which the oxidoreductase is glucose oxidase and the electron mediator is ferrocene carboxylic acid. (Page 1, Lines 11-13)

Ju *et al.* teaches a method of quantitating a glucose in which the working electrode is a rotating disk electrode (Page 541, Column 2, Lines 18-19) or micro-electrode. (Page 541, Column 1, Lines 5-7)

Higgens teaches the use of pyrroquinoline quinine dependent glucose dehydrogenase in a method of quantitating a substrate in a liquid mixture. (Column 4, Line 16-18)

Crumbliss *et al.* teaches the use of hexacyanoruthenate as an electron mediator in a reaction to quantitate a substrate. (Page 327, Line 10)

One of ordinary skill in the art at the time of the instant invention would have been motivated to use a central potential within the range of –0.4 to +0.4 V relative to a redox potential of an electron mediator, that is a potential more positive than a potential that is -0.05 V relative to the most negative potential in a potential region where the reaction of an interfering reaction is diffusion-controlled because these ranges were demonstrated previously by Kuwabata *et al.* to provide a more precise measurement of the electron transfer process separated from the process of diffusion using AC current instead of the less precise and more prone to interference method using DC current.

One of ordinary skill in the art at the time of the instant invention would have been motivated to use a central potential within the range of –0.1 to +0.1 V relative to a redox potential of an electron mediator, that is a potential more positive than a potential that is 0.05 V relative to the most negative potential in a potential region where the reaction of an interfering reaction is diffusion-controlled because these ranges were demonstrated previously by Kuwabata *et al.* to provide a more precise measurement of the electron transfer process separated from the process of diffusion using AC current instead of the less precise and more prone to interference method using DC current.

One of ordinary skill in the art at the time of the instant invention would have been motivated to use impedance because the technique was well known in the art and an advantage to using impedance biosensors is that they are not restricted to use solely with redox enzymes, allowing a greater range of proteins to be used in biosensor detection.

The ordinary artisan would have been motivated to use ferrocene carboxylic acid as an electron mediator in a redox reaction process using glucose oxidase because it was well known in the art that glucose oxidase was an oxidoreductase and that ferrocene derivatives were electron mediators, and that in the case where an electron mediator is required to be diffused throughout a solution it is desirable to use a more soluble ferrocene compound such as ferrocene carboxylic acid.

The ordinary artisan at the time of the instant invention would have been motivated to use microelectrodes or rotating disk electrodes in a method of quantitating a substrate because of the inherent advantages of using microelectrodes or rotating disk electrodes, such as being virtually free of fouling by interfering substance ascorbic acid and more rapid response time.

The ordinary artisan at the time of the instant invention would have been motivated to use pyrroquinoline quinine dependent glucose dehydrogenase or PQQ as the oxidoreductase and ruthenium hexacyanate as the electron mediator in a method of quantifying a substrate, because PQQ has the major advantage of not using oxygen as an electron acceptor, while ruthenium compounds were also known in the art as electron mediators and hexacyanoruthenate was shown to have the optimal characteristics of reversible electrochemistry at the electrode surface and rapidly oxidize an oxidoreducatase.

The ordinary artisan would have been motivated to combine the above teachings based on the advantages discussed above, resulting a in a faster, more precise measurement of electrochemical signal that would enable one of ordinary skill to more accurately measure an particular substrate in a sample even though the sample contained potential interferents. The ordinary artisan would have had a reasonable expectation of success based on the successful use of the techniques and compounds individually and their prior use in similar methods.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

12/14/05

PATRICIA LEITH
PRIMARY EXAMINER